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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/589,777	06/08/2000	Vikas P. Sukhatme	1440.1023-011	1530
29933	7590	02/18/2004	EXAMINER	
PALMER & DODGE, LLP KATHLEEN M. WILLIAMS 111 HUNTINGTON AVENUE BOSTON, MA 02199			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 02/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/589,777

**Applicant(s)**

SUKHATME, VIKAS P.

**Examiner**

MISOOK YU, Ph.D.

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12/21/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 2,4,11-34 and 36 is/are pending in the application.
- 4a) Of the above claim(s) 5-10 and 17-34 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 36 is/are allowed.
- 6) ☒ Claim(s) 2,4 and 11-16 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent, Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☒ Other: sequence alignment.

## **DETAILED ACTION**

### ***Election/Restrictions***

Claims 5-10 and 17-34 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8.

This application contains claims 17-34 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claims 2, 4, 11, 13, and 14 are amended.

Claims 2, 4-34, and 36 are pending and claims 2, 4, 11-16, and 36 are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

This Office action contains new grounds of objection.

### ***Specification,***

The objection of the specification due to an embedded hyperlink and/or other form of browser-executable code is withdrawn because in view of the amendment.

### ***Claim Rejections - 35 USC § 112, Withdrawn***

The rejection of claims under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendment.

***Claim Rejections - 35 USC § 112, Maintained***

Claims 2, 4, and 11-16 remain rejected for reason of record under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims are interpreted as drawn to a genus of protein comprising residues 168-175 of SEQ ID NO:2, wherein said protein has anti-angiogenic activity.

Applicant argues that the amended claims reciting the common structural feature associated with anti-angiogenic activity satisfy written description requirement. The argument has been fully considered but found unpersuasive. The specification teaches only one protein sequences comprising the common structural feature i.e. the mouse endostatin sequences comprising amino acid residues 168-75 of SEQ ID NO:2. The specification at page 9 and 10, and "EM1" in the instant claim 12 reasonably conveys that claimed invention encompasses other mammalian sequences yet to be discovered. Thus, it is concluded that only one disclosed sequence do not represent the entire genus, which encompasses unpredictable species from other mammals.

***Claim Rejections - 35 USC § 102, Withdrawn***

The rejection of claims 2, 4, 11, and 13-15 under 35 U.S.C. 102(a) as being anticipated by O'Reilly et al (IDS AR, Cell, Vol 88, 277-285, 24 January 1997) is withdrawn because the Office interprets that instantly claimed invention is drawn to a deletion mutant lacking the last 9 amino acids of SEQ ID NO:2 as applicant argues.

The rejection of claims 2, 4, 12-16, and 35 under 35 U.S.C. 102(e) as being anticipated by US Pat 5,854,205 (IDS AA, O'Reilly et al) is also withdrawn for the reason given above, under 35 U.S.C. 102(a).

***The Following are the New Grounds of Objection***

***Claim Objections***

Claim 4 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. This objection is based on interpretation of the limitation "the endostatin protein" in line 5 of the base claim 2 is the same as SEQ ID NO:2. The C-terminal "nine consecutive amino acids" of SEQ ID NO:2 is SEQ ID NO:25.

***Claim Rejections - 35 USC § 112***

Claims 2, 4, and 11-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The base claim 2 as construed is still confusing because of the limitation "comprises residues 168-175 and a deletion mutation of an endostatin of SEQ ID NO:2" in the base claim. The transitional phrase "comprises" in line 2 of claim 2 encompasses everything comes after the transitional phrase. The claim could also be interpreted as drawn to a deletion mutant comprising residues 168-175 of SEQ ID NO:2, wherein said

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deletion mutant does not comprises the last 9 amino acids at the C-terminal end of SEQ ID NO:2.

***Claim Rejections - 35 USC § 102***

Claims 2, 4, and 11-16 are rejected under 35 U.S.C. 102(e) as being anticipated by US Pat 6,080,728 (Mixson, issue date June 27, 2000; filing date December 5, 1997).

This rejection is based on the Office interpretation of the claimed invention as construed in the instant claims 2 and 4 as drawn to a polypeptide with two requirements i.e. said polypeptide must **include** (comprises) amino acid residues **168-175 of SEQ ID NO:2** but **must exclude instant SEQ ID NO:25**. Dependent claims 11 and 12 are drawn to fusion comprising the claimed peptide of the base claim. Claims 13-16 are drawn to a composition comprising the polypeptide of base claim as active ingredient and other ingredients, pharmaceutically compatible carrier (claim 14), the fusion protein (claims 15, and 16).

US Pat 6,080,728 at columns 7-8, 49-50 teaches a polypeptide that meets two requirements i.e. comprises amino acid residues 168-175 of SEQ ID NO:2 but exclude instant SEQ ID NO:25. US Pat 6,080,728 also teaches that each of the sequences listed at columns 7 and 8 is anti-angiogenic proteins (note lines 37-39). Note the attached sequence alignments showing that SEQ ID NO:36 of the prior art comprises amino acid residues 168-175 of SEQ ID NO:2 but does not contain instant SEQ ID NO:25. SEQ ID NO:36 of the art appears to meet the limitations of instant claims 11, and 23 because the sequence of the art appears to be a endostatin sequence. The art also teaches pharmaceutically compatible carrier suitable for in vivo administration at

page columns 6 and 7. Thus, US Pat 6,080,728 anticipates instant claims 2, 4, and 11-16.

***Allowable Subject Matter***

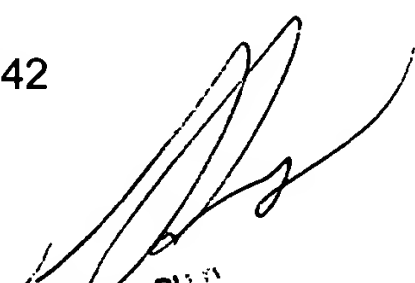
Claim 36 is allowed.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

MISOOK YU, Ph.D.  
Examiner  
Art Unit 1642



LARRY R. HELMS, Ph.D.  
PRIMARY EXAMINER